B6 cont

30. (Amended) An isolated and purified animal cell [Animal cells] which [express] expresses the recombinant polypeptide produced by the method according to claim 28 [and] or 29.

REMARKS

In the Office Action dated April 11, 2000, the specification has been objected to due to certain alleged informalities. Claim 30 has been rejected on 35 U.S.C. §101 as allegedly directed to non-statutory subject matter. Claims 1-10, 25 and 28-30 have been rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. Claims 1-10, 25 and 28-30 have been rejected under 35 U.S.C. §112, first paragraph as allegedly lacking enabling support. Claims 1-8 and 18 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Kausch, et al., U.S. Patent No. 5,508,164 (hereinafter "Kausch"). Claims 1-8 and 18 have also been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Lin, et al. (1975) Science 190:61-62 (hereinafter "Lin"). Claim 1 has been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Nagata, et al., U.S. Patent No. 5,574,136 (hereinafter "Nagata").

In response to the above rejections, applicants have amended the claims, which when considered with the accompanying comments, is deemed to place the present application in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

The specification has been objected to as allegedly containing certain informalities which require amendment. Applicants have inserted appropriate section headings for the

relevant specification sections provided. The Examiner has acknowledged applicants' claim for foreign priority. The Examiner alleges that applicants have not filed a certified copy of applications PN-6135, PN-7276 and PO-2208 as required by 35 U.S.C. §119(b). Applicants respectfully submit that certified copies of the foregoing Australian applications will be filed in due course.

The Examiner alleges that the application must contain a specific reference to prior applications. Applicants respectfully submit that the present application does not require specific reference to prior applications because it is not a non-provisional application claiming the benefit of one or more prior filed co-pending, non-provisional applications or international applications designating the United States of America. The present application was filed under 35 U.S.C. §371 as a national stage of PCT/AU96/00668, which was originally filed in Australia on October 23, 1995 as PN-6135. (See 37 C.F.R. §1.78.)

The Examiner has objected to the drawings allegedly because each figure must be described separately in a BRIEF DESCRIPTION OF THE DRAWINGS. Applicants will amend the BRIEF DESCRIPTION OF THE DRAWINGS, as well as the figure number in accordance with 37 C.F.R. §1.84(u)(1), upon the indication of allowable subject matter.

The Examiner alleges that the application contains two sets of sequence listings, one presented originally as pages 47-57 of the specification and another set submitted on January 6, 1999. Applicants respectfully submit that the sequence listing submitted on January 6, 1999 superseded the sequence listing as originally filed. Pursuant to the Office communication dated December 2, 1998, applicants provided an initial computer-readable form of the "Sequence Listing", together with a substitute paper copy thereof. Thus, the

sequence listing submitted on January 6, 1999, should be relied upon for examination of the present claims on the merits. Applicants further respectfully submit, consistent with the submission of the sequence listing on January 6, 1999, that such sequence listing contained no new matter.

The Examiner alleges that the application fails to comply with the sequence rules 37 C.F.R. §§1.821-1.825. The Examiner alleges that "sequences in figures must be identified by their corresponding "SEQ ID NO" and disclosed in the BRIEF DESCRIPTION OF THE DRAWINGS". Applicants respectfully direct the Examiner's attention to 37 C.F.R. §1.821(d) which provides in relevant part:

> "Where the description of claims of a patent application discuss a sequence that is set forth in the sequence listing in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier ... in the text of the description or claims ..."

Applicants respectfully submit that the specification provides specific reference to sequence ID numbers throughout the specification and claims (as amended) in full compliance with the sequence rules.

Claim 30 has been rejected under 35 U.S.C. §101 as originally directed to non-statutory subject matter. In an effort to further favorable prosecution on the merits, applicants have amended Claim 30 to recite "An isolated and purified animal cell" in accordance with the Examiner's suggestion. Accordingly, the rejection of Claim 30 under 35 U.S.C. §101 is overcome and withdrawal thereof is respectfully requested.

Claims 1-10, 25 and 28-30 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enabling support. The Examiner admits that the specification is enabling

for an isolated DNA (SEQ ID NO:3) encoding an haemopoietin polypeptide (IL-13) comprising SEQ ID NO:4. The Examiner alleges that it would take undue experimentation to identify the other polypeptides of the instant invention.

In response, and in an effort to advance favorable prosecution, applicants have amended Claims 1, 2, 7, 8, 10, 28, 29 and 30 to recite isolated nucleic acid molecules comprising SEQ ID NOS:1 or 3 encoding a haemopoietin receptor having amino acid sequence as set forth in SEQ ID NOS:2 or 4, respectively, consistent with the teachings of the specification at pages 5, line 5, to page 6, line 3, for example.

The Examiner alleges that "the hybridization conditions of Claims 7 and 8 have not been specified ... ". Applicants respectfully direct the Examiner's attention to the specification at page 7, line 23 to page 8, line 2 which provides a description of "low stringency" hybridization conditions commensurate with the requirements of 35 U.S.C.§112, first paragraph. Moreover, it is respectfully submitted that "low stringency conditions" are recognized and well described by standard texts such as Maniatis, et al.

The Examiner further alleges that "derivatives" of the isolated nucleic acid molecules of the present invention are not supported by the teachings of the specification. The Examiner admits, however, that "derivatives of IL-13 can be made [according to the teachings of the specification]". Applicants respectfully direct the Examiner's attention to Example 12, on page 40 of the specification which provides adequate support for derivatives of the claimed nucleic acid molecules. Specifically, Example 12 discloses a derivative, i.e., an extracellular ligand binding domain of the NR 4 coding region of the haemopoietin receptor of the present invention. Example 12 further provides guidance regarding the

identification, isolation and characterization of the receptor derivative. The functionality of the receptor derivative is described as follows:

> "Consistent with the low affinity of IL-13 for NR4 expressed by COS cells, purified soluble NR4 appeared unable to bind IL-13 as assessed by gel filtration chromatography. However, using sensitive cross-linking assays, the ability of soluble IL-13 R α (NR4) to bind IL-13 was demonstrated (Figure 8, lane 1). This interaction was repeated by unlabelled IL-13, but not by unlabelled IL-4 (Figure 8, lanes 2 and 3). (See page 40, line 28-page 41, line 2.)"

Thus, derivatives of IL-13 are disclosed and enabled in accordance with the provisions of 35 U.S.C. §112, first paragraph.

Accordingly, the rejections of Claims 1-10, 25 and 28-30 under 35 U.S.C. §112, first paragraph are overcome and withdrawal thereof is respectfully requested.

Claims 1-10, 25 and 28-30 have been rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. The Examiner has rejected Claims 1, 2, 7, 8 and 29 as allegedly unclear as to the referenced sequence of nucleotides encoding a haemopoietic receptor, so as to allow the metes and bounds of the claims to be determined. In response, applicants have amended Claims 1, 2, 7, 8 and 29 to further favorable prosecution. Specifically, the claims now recite isolated nucleic acid molecules comprising SEQ ID NOS:1 or 3 encoding haemopoietic receptors having amino acid sequence as set forth in SEQ ID NOS:2 and 4, respectively. Thus, the foregoing amendment clarifies the sequence of nucleotides referred to by the claims.

Claims 1-4, 7-9 and 28-29 have been rejected as indefinite allegedly because a "derivative" of said receptor is unclear. Applicants respectfully submit that the term

"derivative" refers to a portion of a defined, continuous sequence of nucleotides contained within the NR4 sequence of the haemopoietin receptor. In accordance with the present invention, a derivative may, for example, encompass the extracellular ligand binding domain or an even shorter portion thereof. Applicants direct the Examiner's attention to Example 12 (discussed above) which describes the preparation, characterization and functionality of a derivative of the haemopoietin receptor of the invention.

The Examiner alleges that the phrase "low affinity" in Claims 3 and 28-29 renders the claims indefinite. Similarly, Claim 4 has been rejected as allegedly indefinite because of the phrase "medium or high affinity". As previously indicated, Claims 3 and 4 have been canceled without prejudice. In an effort to further favorable prosecution, the phrase "low affinity" has been deleted from Claims 28-29.

Claims 5, 6, 7, 8, 28 and 29 have been rejected as allegedly indefinite in view of the recitation "substantially". As indicated above, Claims 5 and 6 have been canceled without prejudice. Claims 7, 8, 28 and 29 have been amended in an effort to further favorable prosecution by deleting the recitation "substantially" therefrom.

The Examiner alleges that Claim 7 is indefinite because the term "functionally similar IL-13 receptor" is unclear. Applicants have amended Claim 7 to delete the recitation "functionally similar IL-13 receptor". The Examiner alleges that Claims 7 and 8 are indefinite because "low stringency conditions" are not specified. Applicants respectfully direct the Examiner's attention to the specification at page 7, lines 23-25 which provides precise conditions under which hybridizations are performed, including wash conditions.

Claim 25 is rejected under 35 U.S.C. §112, second paragraph in view of the recitation "genetically acceptable carrier and/or diluents". Applicants have amended Claim 25 to delete the recitation "genetically" in an effort to further favorable prosecution on the merits. Claims 28 and 29 have been rejected as allegedly indefinite "because it appears that the Western blot is expressed in COS cells". Claims 28 and 29 have been amended in accordance with the Examiner's suggestion to recite that the polypeptide, "when expressed in COS cells, has a molecular weight of from about 50,000 to about 70,000 daltons as determined by Western blot analysis".

Claim 10 has been rejected because the recitation "genetic construct" is allegedly indefinite. Applicants have amended Claim 10 to further favorable prosecution by deleting the recitation "genetic construct" in favor of the recitation "expression vector" as suggested by the Examiner.

Accordingly, the rejections of Claims 1-10, 25 and 28-30 under 35 U.S.C. §112, second paragraph are overcome and withdrawal thereof is respectfully requested.

Claims 1-8 and 18 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Kausch, et al. In the first instance, the Examiner's rejection is not fully understood. Claim 18 has been withdrawn from consideration pursuant to the restriction requirement issued by the Examiner and is not subject to examination in the present case. Therefore, applicants address the rejection of pending Claims 1-8 only. The Examiner alleges that "Claims 1-10, encompass chromosomal DNA because the claims recite nucleic acid comprising the nucleotide sequence of SEQ ID NO:11 or derivatives thereof and Claim 30 encompasses animal cells having the genetic construct of Claim 10". Applicants submit that

the Examiner's rejection does not relate to the pending claims. Assuming the Examiner has rejected Claims 1-8 based on inherent teachings in Kausch, et al., applicants respectfully submit that the claims, as amended, recite an isolated nucleic acid molecule which is neither taught nor disclosed by Kausch, et al. explicitly or implicitly. Accordingly, withdrawal of the rejection of Claims 1-8 and 18 under 35 U.S.C. §102(b) is respectfully requested.

Claims 1-8 and 18 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Lin, et al. (Claim 18 is not elected.) The Examiner alleges that Lin, et al. disclose the isolation of chromosomes from human lymphocytes. The Examiner further alleges that Claims 1-10 and 30 encompass chromosomal DNA and cells containing chromosomal DNA because the claims recite nucleic acids comprising the nucleotide sequence of SEQ ID NO:3. Applicants respectfully submit that Lin, et al. fail to teach the isolated nucleic acid molecules presently claimed. Withdrawal of the rejection of Claims 1-8 under 35 U.S.C. §102(b) is, therefore, respectfully requested.

Claim 1 has been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Nagata, et al. The Examiner alleges that Nagata, et al. "disclose an isolated nucleic acid molecule comprising G-CSF, a human haemopoietin factor ... thereby meeting the limitation of Claim 1". Applicants respectfully submit that the claims, as amended, recite a nucleic acid molecule comprising SEQ ID NO:1 or 3 encoding a haemopoietin receptor which is neither taught nor disclosed by Nagata, et al. Accordingly, rejection of Claim 1 under 35 U.S.C. §102(b) is overcome and withdrawal thereof is respectfully requested.

Thus, in view of the foregoing amendments and remarks, applicants respectfully submit that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

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